

Application No. 09/626,636  
Reply dated November 6, 2008  
Reply to Final Office Action of August 6, 2008

### **REMARKS**

In the Office Action, the Examiner rejected claims 172-176, 178-184, 201, 202, 247, 331, and 344-346 (including independent claim 172) under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,878,915 to Brantigan ("Brantigan"), U.S. Patent No. 5,108,395 to Laurain ("Laurain"), and U.S. Patent No. 5,049,150 to Cozad ("Cozad"). Furthermore, the Examiner also rejected claims 248-256, 258-269, 276, 278-286, and 347-349 (including independent claim 248) under 35 U.S.C. § 103(a) as being unpatentable over Brantigan, Laurain, and Cozad. As discussed below, Applicant submits that independent claims 172 and 248 are patentable over the Examiner's rejections thereof under 35 U.S.C. § 103(a) based on Brantigan, Laurain, and Cozad.

In KSR International Co. v. Teleflex Inc. et al., the Supreme Court reaffirmed the framework for governing obviousness under 35 U.S.C. § 103(a) as set forth in Graham et al. v. John Deere Co. of Kansas City et al., 383 U.S. 1, 148 U.S.P.Q. 459 (1966). (See KSR v. Teleflex, 127 S.Ct. 1727 (2007).) Under Graham v. John Deere, the question of obviousness is resolved on the basis of factual determinations including (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the pertinent art, and (4) where in evidence, so-called secondary considerations. (See Graham v. John Deere, at 17-18, 148 U.S.P.Q. at 467.) However, even under Graham v. John Deere, references that teach away from a combination thereof, or a combination of references that does not teach or suggest every element of the claimed invention support a finding of nonobviousness. Applicant submits that Brantigan and Cozad teach away from Laurain, and that, even if the combination of Brantigan, Laurain, and Cozad was viable, the combination thereof does not teach or suggest each and every limitation of Applicant's invention as claimed in independent claims 172 and 248.

Laurain is directed to an implant (1) for permanent affixation within a patient. The implant (1) includes two clamps (2) that are each permanently affixed to a vertebral body, and a rigid plate (6) for interconnecting the two clamps (2). Each of the two clamps (2) include surfaces directed toward and away from the vertebral bodies, and a

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tubular part (12) having threads (13) and (20). The threads (20) are used for attaching the tubular parts (12) to the two clamps (2), and the threads (13) are used for attaching the rigid plate (6) to the two clamps (2). To attach the rigid plate (6) to the two clamps (2), the threads (13) of the tubular parts (12) are received through orifices (17) in the rigid plate (6), and nuts (7) are threadably engaged to the threads (13).

The surfaces of the two clamps (2) of Laurain that are directed toward the vertebral bodies are contoured to complement the vertebral bodies. Furthermore, as depicted in Fig. 3B, the end portions of the tubular parts (12) facing the vertebral bodies appear to be contoured to complement the vertebral bodies. However, the end portions of the tubular members (12) are contoured such that the middle portion thereof is not closer to the proximal end of the tubular member (12) than at least one of the opposed side portions thereof. As such, Laurain teaches that at least one of the opposed side portions of the end portions is the same distance from the proximal end of the tubular members (12) as the middle portion.

Brantigan discloses the drill guard (22) including teeth or prongs (23). The teeth (23) of Brantigan appear to terminate at a plane perpendicular to the longitudinal axis of the drill guard (22). Furthermore, Cozad discloses the second member (14) including a plurality of teeth (36) for passing a drill-tipped first member (12) therethrough. Like the teeth (23) of Brantigan, the plurality of teeth (36) also appear to terminate at a plane perpendicular to the longitudinal axis of the second member (14). Both the teeth (23) of Brantigan and plurality of teeth (36) of Cozad engage bone. However, neither of the ends of Brantigan and Cozad including the teeth (23) and the plurality of teeth (36), respectively, are contoured to complement the shape of the bone being contacted.

Given that the ends of the drill guard (22) (of Brantigan) and the second member (14) (of Cozad) including the teeth (23) and the plurality of teeth (36), respectively, terminate at a plane perpendicular to the longitudinal axes of their respective instruments, and Laurain teaches that at least one of the opposed side portions of the end portions is the same distance from the proximal end of the tubular members (12) as the middle portion, Applicant submits that the combination of Brantigan, Laurain, and

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Cozad does not teach or suggest each and every limitation of independent claims 172 and 248. Unlike independent claims 172 and 248, Brantigan, Laurain, and Cozad do not teach or suggest an apparatus for use in performing human interbody surgery including a hollow tubular guard (claim 172) or a hollow guard (claim 248) with a distal end having "a concave curvature being at least in part curved in a single plane parallel to the mid-longitudinal axis," where the concave curvature of the distal end has "a middle portion and opposed portions on either side of said middle portion, said middle portion being closer to said proximal end than said opposed portions." Accordingly, the Examiner's rejection of independent claims 172 and 248 under 35 U.S.C. § 103(a) based on the combination of Brantigan, Laurain, and Cozad fails.

Furthermore, Applicant submits that Brantigan and Cozad teach away from Laurain. Laurain teaches that when contacting a vertebral body, the surfaces of the two clamps (2) directed toward the vertebral bodies are contoured (albeit differently from the distal ends of the hollow tubular guard (of claim 172) or the hollow guard (of claim 248)) to complement the contacted vertebral body. However, when contacting bone (and contrary to Laurain), the ends of the drill guard (22) (of Brantigan) and the second member (14) (of Cozad) including the teeth (23) and the plurality of teeth (36), respectively, terminate at a plane perpendicular to the longitudinal axes of their respective instruments. Neither of the teeth (23) of Brantigan and plurality of teeth (36) of Cozad are contoured to complement the shape of the bone being contacted. As such, given the considerably different configurations of Brantigan and Cozad in comparison to Laurain, Applicant submits that Brantigan and Cozad teach away from Laurain. Accordingly, Applicant again submits that the obviousness rejection of independent claims 172 and 248 based on a combination of Brantigan, Laurain, and Cozad fails, and hence, cannot be maintained.

Additionally, the Examiner rejected independent claim 350 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan, Laurain, Cozad, and Codman (Ruptured Cervical Intervertebral Discs article). As discussed above, given the configuration of the teeth (23) of Brantigan and plurality of teeth (36) of Cozad (where

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neither are contoured to complement the shape of the bone being contacted), Brantigan and Cozad teach away from a combination with Laurain. In similar fashion, the surface of the drill guide of Codman, as shown in Fig. 21 thereof, for contacting bone appears to be flattened, and hence, is not contoured to complement the shape of the bone being contacted. Therefore, like Brantigan and Cozad, Codman also teaches away from a combination with Laurain. Accordingly, Applicant submits that the obviousness rejection of independent claim 350 based on Brantigan, Laurain, Cozad, and Codman cannot be maintained.

The Examiner rejected claims 207, 208, 210-212, 215-218, 220-226, 237, and 238 (including Independent claim 207) under 35 U.S.C. § 103(a) as being unpatentable over Brantigan, Cozad, and U.S. Patent No. 3,486,505 to Morrison ("Morrison"). Independent claim 207 recites an apparatus for use in performing human interbody spinal surgery including a hollow tubular guard having "at least two slots in said sides, said slots divide at least a portion of said guard into an upper portion and a lower portion, said upper portion and said lower portion being adapted to move apart from one another to facilitate insertion of an implant." As discussed below, Applicant submits that Morrison teaches away from a combination with Brantigan and Cozad.

Morrison is directed to an orthopedic instrument (B) including arms (11) mounted for movement toward and away from one another. The arms (11) are spaced apart from one another over almost the entirety of their lengths. Although the arms (11) along with spaced lateral guides (16) define a channel (13) therebetween, the orthopedic instrument (B) is not tubular. Instead, the arms (11) are flat portions articulatable relative to one another about a handle (17) adjacent one end of the orthopedic instrument (B). Given that the drill guard (22) of Brantigan and the second member (14) of Cozad (contrary to the teachings of Morrison) are tubular, Applicant submits that Morrison teaches away from Brantigan and Cozad. Accordingly, Applicant submits that the obviousness obviousness rejection of independent claim 207 based on Brantigan, Morrison, and Codman cannot be maintained.

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The Examiner rejected claims 289-304, 306-318, and 323-329 (including independent claim 289) under 35 U.S.C. § 103(a) as being unpatentable over Brantigan, Cozad, and Codman. As discussed above, Brantigan discloses the drill guard (22), Cozad discloses the second member (14), and Codman discloses the drill guide, each of which are provided for passing a drill therethrough. Brantigan, Cozad, and Codman do not teach or suggest passing an implant through the drill guard (22), the second member (14), and the drill guide, respectfully. Accordingly, neither Brantigan, Cozad, nor Codman teach or suggest an apparatus for use in human lumbar interbody spinal surgery including "a hollow guard having a passage for providing guided access to a disc space and vertebral bodies adjacent the disc space to pass an implant therethrough," "an implant sized for passage through said passage of said guard," and "an implant driver sized in part for passage through said passage of said guard for passing said implant through said guard and into an implantation space," as recited in independent claim 289. Accordingly, Applicant submits that the obviousness rejection of independent claim 289 based on Brantigan, Cozad, and Codman cannot be maintained.

The Examiner rejected claims 332, 335-337, 339, and 341-343 (including independent claim 332) under 35 U.S.C. § 103(a) as being unpatentable over Brantigan and Cozad. However, neither Brantigan nor Cozad include an apparatus for use in human lumbar interbody spinal surgery including a hollow guard having "a wall that is continuous around the mid-longitudinal axis of said guard," and "an opening through said wall," as recited in independent claim 332. Accordingly, Applicant submits that the obviousness rejection of Independent claim 332 based on Brantigan and Cozad cannot be maintained.

Additionally, the Examiner rejected claims 190-195 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Laurain and Cozad as applied to claim 172 above, and further in view of Codman, rejected claim 219 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cozad and Morrison as applied to claim 207 above, and further in view of Laurain, rejected claims 270-275 under 35

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U.S.C. § 103(a) as being unpatentable over Brantigan in view of Laurain and Cozad as applied to claim 248 above, and further in view of Codman, rejected claims 287 and 288 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Laurain and Cozad as applied to claim 286 above, and further in view of U.S. Patent No. 5,357,983 to Mathews ("Mathews"), rejected claim 305 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cozad and Codman as applied to claim 289 above, and further in view of Laurain, rejected claims 329 and 330 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cozad and Codman as applied to claim 328 above, and further in view of Mathews, rejected claims 333 and 334 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cozad as applied to claim 332 above, and further in view of Mathews, rejected claim 338 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cozad as applied to claim 332 above, and further in view of Laurain, and rejected claim 340 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cozad as applied to claim 332 above, and further in view of Codman. Applicant submits that the rejections of claims 190-195, 219, 270-275, 287, 288, 305, 329, 330, 333, 334, 338, and 340 are rendered moot at least because these claims depend from an allowable independent claim, or claims dependent therefrom.

Applicant submits that independent claims 172, 207, 248, 289, 332, and 350 are patentable and that dependent 173-176, 178-184, 190-195, 201, 202, 208, 210-212, 215-226, 237, 238, 247, 249-256, 258-276, 278-288, 290-318, 320-331, and 333-349 dependent from one of independent claims 172, 207, 248, 289, or 332, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, Applicant submits that the claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

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To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

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